

REMARKS

Claims 1, 16, 19-20 were rejected on the ground of nonstatutory obviousness-type double patenting in view of commonly assigned US Pat. 7,270,634 (Scampini et al.) The Examiner has stated that a terminal disclaimer may be used to overcome this rejection. Enclosed is a terminal disclaimer which is in compliance with 37 CFR 1.321(c). It is respectfully submitted that this terminal disclaimer overcomes the double patenting rejection.

Claims 1-2, 6 and 11-20 were rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 6,221,016 (Hayakawa). Amended Claim 1 describes a method of ultrasonically displaying an invasive medical device and the volumetric region of a body in which it is located comprising scanning the volumetric region with beams transmitted by an ultrasonic array transducer; receiving echo signals from the volumetric region and from an invasive medical device located in the region; processing echo signals to produce a wide field of view of the volumetric region; processing echo signals to produce a detailed view of the portion of the volumetric region in which the invasive medical device is located; and displaying both the wide field of view of the volumetric region and the detailed view of the portion of the volumetric region in which the invasive medical device is located in spatial alignment in a common image on an image display. An embodiment of the present invention will show an invasive device in a three dimensional view so that the device will always be in view even if its path of travel diverges, a problem when trying to use 2D imaging to follow an invasive device. In that case, when the invasive device moves out of the image plane it (and particularly its tip) is no longer visible in the image plane, a problem cited by Hayakawa for doing 3D imaging. The present invention extends this concept with an additional enhancement by embedding or spatially aligning the volumetric region containing the invasive device in a wide field of view image from the same array transducer. This common image thus shows the invasive device in detail to allow precise guidance of the device, and in the larger context of the wide field of view so that the larger anatomy in which the device is operating is also visible. Since detailed views generally entail greater scanning or more processing than wider fields of view, the additional effort is confined to the volumetric region where it provides the greatest benefit, around the device, and not throughout the entire image. This conservation of scanning or processing enables the common image to be produced more easily, at a better real time frame rate of display, or both.

Hayakawa describes three dimensional imaging of an invasive device in column 11 as cited by the Examiner, and in detail in columns 32-33 of the patent with particular reference to Figs. 19 and 20. Fig. 19 outlines the volumetric region around the invasive device which is scanned in 3D, and Fig. 20 shows a typical 3D image of the region. However, Hayakawa does not align or embed this 3D volume with a wider field of view image, from the same transducer or otherwise. Only a small 3D image around the tip of a device is shown or suggested. In fact, Hayakawa cautions against the thinking of the present invention in column 33, lines 14-22, where he advises the reader to confine the 3D imaging to only the tip of a needle. He does suggest enlarging the image as described in an earlier embodiment of his patent. The concept of displaying a volumetric region containing an invasive device which is embedded in a larger wide field of view in a common image is wholly absent from Hayakawa. For this reason it is respectfully submitted that Claim 1 and its dependent claims cannot be anticipated by Hayakawa.

Amended Claim 16 describes an ultrasonic surgical guidance imaging system which acts to guide the placement or observe the operation of an invasive medical device comprising an ultrasonic probe including an array transducer which steers ultrasonic beams over a volumetric surgical region which includes an invasive medical device; a transmit beamformer coupled to the array transducer which acts to control the spatial beam density of the beams transmitted by the array transducer in the volumetric region; a receive beamformer coupled to the array transducer and responsive to echo signals from array elements for the production of received scanlines in the vicinity of the invasive medical device and in the volumetric region at locations removed from the invasive medical device location; an image processor responsive to the received scanlines for producing a wide field of view image of the volumetric surgical region and a detailed view of the invasive medical device; and a display coupled to the image processor which displays the wide field of view image of the volumetric surgical region with the detailed view of the invasive medical device in spatial registration with and contained within the wide field of view image. This claim describes an ultrasound system with a probe that scans a volumetric region to produce a wide field of view image of a surgical region with a three dimensional view of the sub-region of the invasive device in spatial registration in the wide field of view image. The inventive systems provides similar benefits as the method of Claim 1.

Hayakawa, as previously mentioned, only shows producing a 3D image closely around the tip of an invasive needle. He cautions against extending the region being scanned in 3D, suggesting that if a more precise view is needed, resort be had to an "enlarge"

mode which is an alternate display mode that zooms up the size of the image. Hayakawa does not suggest, and in fact teaches away from, using a probe to produce a wide field of view image and a detailed three dimensional view of a sub-region within the wide field of view which encompasses the invasive device. For this reason it is respectfully submitted that Claim 16 and its dependent Claims 18, 19 and 22 cannot be anticipated by Hayakawa.

Claims 3-5 and 7-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hayakawa in view of US Pat. pub. 2002/0049375 (Strommer et al.) All of these claims ultimately depend from amended Claim 1, and it is seen that the combination of Hayakawa and Strommer et al. do not render Claim 1 unpatentable. The Examiner points to the GUI displays of Figs. 16B and 16C of Strommer et al. On the left side of Fig. 16B is a 3D image 736 with a surgical tool graphic 738 overlaid on the 3D image. On the right side of Fig. 16B is a 2D navigation image 758 with a 2D projection image 754 superimposed on top of it. See paragraph [0240] of Strommer et al. Thus, Fig. 16B shows a 3D image alone, and a 2D image superimposed on another 2D image. Fig. 16C shows the same thing, a 3D image 766 by itself on the left, and a 2D projection image 774 on a two dimensional image 772. Like, Hayakawa, Strommer et al. does not show or suggest spatially aligning or embedding a smaller volumetric image of the region of an invasive device in a wide field of view of the volumetric region. Accordingly it is respectfully submitted that the combination of Hayakawa and Strommer et al. cannot render Claim 1 or its dependent Claims 4-5 and 8-10 unpatentable.

New dependent Claims 21 and 22 have been added which recite that the wide field view portion of the common image and the detailed view of the volumetric region of the invasive device may exhibit different frame rates of display. This is supported by the paragraph spanning pages 12-13 of the specification. It may be desirable to refresh the detailed view of the invasive device at a higher rate for display than the wider field of view so that greater precision in guiding the invasive device is afforded, for example. Since these claims depend from Claims 1 and 16, it is respectfully submitted that they are patentable by reason of their dependency.

To complete the citations in this case, the references cited in companion cases serial numbers 10/550,212 and 10/550,214, the latter being handled by the current Examiner, are listed in the enclosed information disclosure statement. It is respectfully submitted that the Examiner approve entry of these citations in this case.

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1-2, 6, 11-16 and 18-22 are not anticipated by Hayakawa and that Claims 4-5, 8-10,

and 21-22 are patentable over Hayakawa and Strommer et al. Accordingly it is respectfully requested that the rejection of Claims 1-2, 6, 11-16 and 18-20 under 35 U.S.C. §102(b) and of Claims 4-5 and 8-10 under 35 U.S.C. §103(a) be withdrawn. It is further respectfully requested that new Claims 21 and 22 be allowed. It is also respectfully requested that the double patenting rejection be withdrawn in light of the terminal disclaimer.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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